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10th February, 1984

Dr. C. A. Ludlam
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Dear Christopher,

It is still rather early to give you a final specification for our new FVIII product as we really need to have information from a number of batches, processed at least at the pilot-scale. However, from our laboratory data I would estimate that the specific activity should be about 1 iu/mg protein with the total protein being about 30% fibrinogen. Our current product has a specific activity of about 0.35 iu/mg with the total protein being about 60% fibrinogen. Hence the new product should have something like a 3-fold reduction in total protein and a 4-fold reduction in fibrinogen content per iu FVIII.

My question concerning the use of the second batch of heated FVIII derived from two considerations:-

(1) The first batch of heated FVIII, which you very kindly tested, was of a lower quality than we had intended. Because you had been the only person who had been given this somewhat "inferior" batch I felt that it was only fair that you should have the opportunity to try the second "superior" batch also. We have therefore held 8 vials of this batch in the East (with Dr. Boulton). The remainder of the lot was sent to the West and has probably all been used.

(2) The second batch did not give rise to reactions but I wonder if the tests in Glasgow (single infusions in three separate patients) may have been less severe than that carried out by yourself (3 infusions in the same patients). Because there is probably only enough material left for one dose then it seemed to me that further information concerning safety (compared to batch 1) could only be achieved by infusing this into the haemophiliac who received the first lot.

The question that I feel we have to ask now is how much effort should we put into discovering the cause(s) of the reaction in your patients. Perhaps there may be other ways of pursuing this point instead of continuing to use this particular patient as a "Guinea pig"? (eg Dr. Cash's suggestion concerning animals).

We/

We have looked out our dmaa on the IgG content of PFC FVIII and it is approximately 3 g/l (ie about 60mg per vial). We do not have corresponding data for DEFIX but Tom McQuillan is looking at this now and I will send the results to you when he has finished.

Best wishes.

PETER R. FOSTER

c.c. Dr. J. D. Cash